Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Special Nutritionals

ARMS#

12941

0 - FRONT

Fax [redacted]
email - Ladam@bangate.fda.go

Original Text
From: [redacted], on 6/1/98 11:52 PM:
To: Laura Adam@OR@FDACVM

Maybe you can help me with this. If not, please forward this to someone who can. I am trying to get the FDA's attention on this one because it appears to be a very harmful one.

I was searching through your orange book online at
http://www.accessdata.fda.gov/ob/
and I noticed this one dietary suppliment that seems to be getting recognition is not coming up. The name of the Dietary Suppliment is Metabolife 356. The active ingredient is Chromium Picolinate.
Here is the name, address, and phone number off the bottle:
Metabolife International, Inc.
5070 Santa Fe Street
San Diego, CA 92109
(619)490-5222
(800)717-7714 (Re-Order)

If the FDA did not yet approve this, I implore you, DO NOT! If the FDA did already approve this, I beg of you, RECONSIDER!

Reasoning: I first heard of this on the radio, with its one month money back guarantee, and thought that it did not hurt to try. The DJ said a staff member was doing well, so I ordered one bottle, and started taking it according to the directions. For a little while, I was noticing a little improvement. Then, I ordered a few bottles, figuring that since it was working in less than a month, it is good. About 2 months into the program, I had trouble using the bathroom. (This never happened before!) I stopped taking the product, and it got better. I thought this was just a "per chance" incident, and I went back to using the product. Then, I not only had trouble using the bathroom, but I got deathly ill, and almost died. After taking the suppliment for a few days, my temperature went from 98.6 (normal) to about 104 or 105 in less than 24 hours. The [redacted] prescribed medicine and instructed me to go to the emergency room immediately if my temperature goes up even 1/2 a degree, and continued to explain that I could die from body temperatures this high. I was in bed with 2 blankets, shivering like crazy. (I never got this sick before!) I had 2 closed bottles of the product, and one open one. I immediately threw out the open one, and have not taken them in almost a year. Since then, I have not had either of these problems.

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Further Reasoning: While I was doing good with the product (for that 2 to 3 week period) I told a couple of friends about it. One friend

cramped up like crazy within a month after taking the product. When she stopped taking it, the cramps went away. She thought this might just be a coincidence, so she started taking the product again. The cramps came back again, and worse than before. She stopped taking the product since then, and did not have any cramps since then. The other friend stopped talking to me for some reason. In fact, I have not seen the other friend since about 1 month after I mentioned the product.

Final bit of reasoning: before taking the product, I would easily be able to lose weight by exercising. In a month, I would be down at least 6 pounds. After taking the product, I waited several months, and I started exercising. It has been 5 and a half months of intense exercise, and I have not lost more than three pounds.

PLEASE!!! Do some reasearch on this product. There is evidence here pointing to Metabolife being harmful.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
FOOD AND DRUG ADMINISTRATION

COMPLAINT / INJURY REPORT 12941

1. COMPLAINT NUMBER: FLA 9663

2. DATE OF COMPLAINT (Month / Day / Year): 6/10/98

3. FORM OF COMPLAINT
a. (1) [x] TELEPHONE (2) [ ] LETTER (3) [ ] VISIT

4. SOURCE OF COMPLAINT
a. (1) [x] CONSUMER (2) [ ] GOVERNMENT [ ] L [ ] S [ ] F (3) [ ] TRADE SOURCE (4) [ ] OTHER (Indicate in Remarks)

5. COMPLAINANT IDENTIFICATION
a. NAME AND ADDRESS [redacted]
b. AREA CODE AND TELEPHONE NUMBER
HOME [redacted]
WORK [redacted]

6. COMPLAINT OR INJURY
a. [redacted] OF COMPLAINT / INJURY
Consumer initially experienced constipation when he first took it on 3/97. At that time he took it for several months. After stopping, symptoms disappeared. He took again after a couple of weeks (6/97) and after taking 3 days (3 doses).

b. DOES COMPLAINANT EXPECT ADDITIONAL FDA CONTACT?
(1) [x] NO (2) [ ] YES
(If "Yes" Explain in Remarks)

7. INJURY OR ILLNESS RESULTED
(1) [ ] NO
(2) [x] YES *
*(If "yes" complete items a through d)

a. EIB (HFC - 161) NOTIFIED
(1) [ ] NO
(2) [x] YES
DATE: 6/10/98

b. TYPE SYMPTOMS / ONSET (HR.)
(1) [ ] VOMITING
(2) [ ] NAUSEA
(3) [ ] DIARRHEA
(4) [x] FEVER
(5) [ ] SKIN/EYE IRR.
(6) [ ] HEADACHE
(7) [x] OTHER

c. ATTENDING HEALTH PROFESSIONAL?
(1) [ ] NO (2) [x] YES
(If "Yes" give name, address, and phone number)
[redacted]

d. HOSPITALIZATION REQUIRED?
(1) [ ] NO (2) [ ] YES
(If "Yes" give name, address, phone number and dates)

8. PRODUCT AND LABELING
a. BRAND NAME: Metabolife 365
b. PRODUCT NAME: Chromium Picolinate
c. SIZE AND PACKAGE TYPE: 100 TAB.
d. NAME AND LOCATION OF STORE WHERE PURCHASED: MAIL ORDER
e. PACKAGE CODE / SERIAL NUMBER / ETC.: UNK → bottle destroyed
EXP. / USE BY DATE: ____
f. DATE PURCHASED: 0/9.5/97
g. PRODUCT USED (If "Yes" enter date) (1) [ ] NO (2) [ ] YES Date: 6/97
h. AMT. REMAINING: one unopened bottle

9. MANUFACTURER / DISTRIBUTOR OF PRODUCT
a. HOME DISTRICT: LOS-DO
b. C.F. NO.: NO CFN
c. NAME AND LOCATION OF FIRM (Include ZIP Code): Metabolife Int'l, Inc 5070 Santa Fe St. SAN DIEGO, CA 92109 619-490-5222
d. IMPORT PRODUCT (1) [x] NO (2) [ ] YES

10. EVALUATION AND DISPOSITION
a. PROBLEM KEY WORD
(1) CODE: RX
(2) DESCRIPTION: fever

b. EVALUATION
(1) [ ] NOT AN FDA OBLIGATION
(2) [x] OBLIGATION, NO VIOLATION
(3) [x] FDA ACTION INDICATED
(4) [ ] INSUFFICIENT INFORMATION UNABLE TO EVALUATE

b. DISPOSITION
(1) [ ] IMMEDIATE FOLLOW-UP
(2) [ ] F/U NEXT EI
(3) [ ] CLOSED WITHOUT FURTHER INVESTIGATION
(4) [ ] REFERRED TO OTHER FEDERAL AGENCY (Closes File)
(5) [ ] REFERRED TO STATE / LOCAL AGENCY (Closes File)
(6) [x] REFERRED TO OTHER FDA LOS DISTRICT
(7) [ ] REFERRED TO OCI

11. PRODUCT CODE: 54YBA99

12. INFORMATION COPIES TO:
[ ] HFM-650
[ ] HFD-730
[ ] HFV-210
[x] OTHER LOS-DO
[ ] HFZ-343
[x] HFC-~~161~~ 130
[x] HFS-635

13. REMARKS
(6/97) (con't) he again had difficulty urinating / constipation and high fever 104°-105° requiring medical visit.
* See attached Adverse Reaction Form # see adverse reaction report attached

14. NAME AND TITLE OF DISPOSITION OFFICIAL
M Delisle CCC

15. DATE: 6/10/98

FORM FDA 2516 (1/96)

* U.S. GPO: 1997-521-557/85348

Adverse Reaction Information Form A

Complaint Number: FLA 9663 Investigator: Phil Palisi

Consumer Information

Date of Report: 06-03-98 MM/DD/YY

Initial Report Source: ☒ORA Consumer Injury ☒Telephone ☐Correspondence ☐MedWatch ☐USP ☐PQRS ☐Poison Control ☐CDC

Name: [redacted]

Gender: ☐F ☒M

Age: 20

Race: ☐1-White ☐2-Black ☐3-Asian/Pacific Islander ☐4-Native American ☐5-Hispanic ☐8-Other _____ ☐9-Unknown

Information on Adverse Reaction

Date of Adverse Reaction:

Previous Reaction to Product Type: ☒Yes ☐No

Give the site of consumption/ingestion (e.g. home, restaurant, office): home

Describe the adverse event (including symptoms and the time lapse from using product to onset of symptoms): see 251a + attach - high fever (105°F) - constipation

How long did the symptoms last? 24 hrs.

Give the circumstances of exposure (e.g., dose, route of exposure, frequency, etc.). oral, 3 daily doses one per day

List all Medication(s), Dietary Supplement(s), Food(s), and other product(s) used at the time of the event: V.T.C & UNTD

Did event abate after use of suspected product stopped or dose reduced: ☒Yes ☐No ☐Unknown

Did symptoms reoccur after reintroduction of suspected product: ☒Yes ☐No ☐Unknown ☐Not Applicable

Did symptoms reoccur after using other products with the same ingredients: ☐Yes ☐No ☒Unknown ☐Not Applicable

Medical Information

Was a health care provider seen?: ☒Yes ☐No

Give health care provider's name, address and t[redacted] also phone num & trunk nos)

Occupation of Health Care Provider: ☒MD ☐Osteopath ☐Naturopath ☐Nurse ☐Pharmacist ☐Other (specify) _____

What medical tests were performed and what were the results? STREP Throat - neg

What was the medical diagnosis? NONE (DIDN'T TELL THEM about product)

What treatment(s) was given (e.g., drugs, other)? Drugs - Don't remember but to bring down fever.

Were there any preexisting condition(s)/treatment(s)?

(If YES, list them including allergies, and chronic diseases): ☐Yes ☒No

Product Category

1. Adverse reaction to:
   - ☐Medical Food (under medical supervision) ☐Infant Formula
   - ☒Dietary Supplement (a vitamin; an essential mineral; a protein; a herb or similar nutritional substances including botanicals such as ginseng and yohimba; amino acids; extracts from animal glands; garlic extract; fish oils; oil of evening primrose; fibers such as psyllium and guar gum; compounds not generally recognized as food or nutrients, such as bioflavonoids, enzymes, germanium, nucleic acids, para-amino-benzoic acid, and rutin; and mixtures of these ingredients.)
   - ☐Other (traditional food) _____

Other Product Problems

2. ☐Foreign Object (specify): _____
3. ☐Other (specify): _____

Information on Suspected/Alleged Product

Give the product name (including dose/serving size, duration of use, and reason for taking):
"Metabolite 356" brand of Chromium Picolinate

List product ingredients (if ingredients are suspected to be present, but not verified, list as suspected):
☐Check here if ingredients are unknown
Chromium Picolinate (Active Ingred - the only one)
356mg

If a particular ingredient is suspected of contributing to the reaction, please indicate the appropriate category below:

☐Aspartame ☐Color Additive (please specify) _____
☐Monosodium Glutamate
☐Sulfite
☐Other _____
☒Unknown

Product Label Available: ☒Yes ☐No ☐Unknown Product Sample Available: ☒Yes ☐No ☐Unknown

Outcome Attributed to Adverse Event:
(If yes, include pertinent medical records)

Death: ☐Yes ☒No

Life-Threatening: ☐Yes ☒No

Hospitalization: ☒Yes ☐No (if YES, indicate if initial or prolonged) E.R. only - [redacted]

Required intervention to prevent permanent impairment/damage: ☐Yes ☒No

Did the adverse reaction result in a congenital anomaly: ☐Yes ☒No

FLA 9613 6-10-98

To: Philip DeLisle@ORL@FDAORASER
Cc: Margaret Leake@MIA@FDAORASER
Bcc:
From: M. Anthony Abel@NSV@FDAORASER
Subject: Complaint on Metabolife 365
Date: Wednesday, June 3, 1998 8:58:54 EDT
Attach:
Certify: Y
Priority: Normal
Defer until:
Expires:
Forwarded by:

Phil/Margaret:

How are things in Sunny Florida. We're having a bit of a heat wave with temperatures in the mid 90's and heat indices in the low 100's.

I received e-mail's (see below) from a gentleman in [redacted] describing an adverse reaction to Metabolife 365, a "dietary supplement" for weight loss. I, too, have heard advertisements for this product on the radio. In my communication with him, I told him I would request that someone from the nearest FDA office contact him.

Would one of you be kind enough to contact Mr. [redacted] and generate a complaint? You may also wish to inquire about his friend(s) who also experienced an adverse reaction to this product.

With the consumer being in the [redacted] area, I didn't know whether to send to [redacted] or [redacted] Therefore, I did the only logical thing and sent it to both. I figured that way I wouldn't be stepping on either of your toes. Take care and keep in touch.

Thanks. /Tony

To: M. Anthony Abel@NSV@FDAORASER
Cc:
Bcc:
From: [redacted]
Subject: [illegible], Harmful, Dietary Supplement
Date: Monday, June 1, 1998 22:46:58 CDT
Attach: Headers.822
Certify: N
Priority: Normal
Defer until:
Expires:
Forwarded by:

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PLEASE!!! Do some reasearch on this product. There is evidence here pointing to Metabolife being harmful.

To: SMTP@FDAORAHQ05@Servers [redacted]
Cc:
Bcc:
From: M. Anthony Abel@NSV@FDAORASER
Subject: re: legal, harmful, Dietary Supplement
Date: Tuesday, June 2, 1998 7:54:52 CDT
Attach:
Certify: N
Priority: Normal
Defer until:
Expires:
Forwarded by:

Mr. [redacted]

I have read your e-mail this morning and would like for you to file a complaint with FDA.

If you could again e-mail me at "MAAbel@ora.fda.gov" and provide me with your address and a telephone number where you can be reached during normal business hours, I will forward that information to the FDA office nearest to you. You will then be contacted and requested to provide specific information about the reaction you experienced.

Your friends (at least the one that is still talking to you) may also wish to file a complaint. You may be asked to provide authorization for release of your medical records (RELATING TO THIS INCIDENT ONLY) so that we can have our medical officers review them against other reports, if any exist, of adverse experiences to Metabolife 356.

Upon receipt of your address and telephone number, again during normal

business Hours, I will promptly notify the FDA closest to your residence. I look forward to hearing from you at your earliest convenience.

M. Anthony Abel, I
Supervisory Investigator
FDA/Nashville District Office
(615) 781-5385

To: M. Anthony Abel@NSV@FDAORASER
Cc:
Bcc:
From: [redacted]
Subject: Re: Legal, harmful, Dietary Supplement
Date: Tuesday, June 2, 1998 18:21:10 CDT
Attach: Headers.822
Certify: N
Priority: Normal
Defer until:
Expires:
Forwarded by:

Thank-you for your prompt reply. My info is as follows:

[redacted] (home)
[redacted] (office)

[end of message]